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| APPLICATION NO. | F                                     | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|-----------------|---------------------------------------|------------|----------------------|-------------------------|------------------|--|
| 09/646,224      | 6,224 09/14/2000                      |            | David Thomas Grose   | 1430-252                | 5556             |  |
| 23117           | 7590                                  | 09/07/2005 |                      | EXAM                    | EXAMINER         |  |
|                 |                                       | RHYE, PC   | LANDSMAN             | LANDSMAN, ROBERT S      |                  |  |
|                 | GLEBE ROAD, 11TH FLOOR<br>N, VA 22203 |            |                      | ART UNIT                | PAPER NUMBER     |  |
| ŕ               |                                       |            |                      | 1647                    |                  |  |
|                 |                                       |            |                      | DATE MAILED: 09/07/2005 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | V   |              |  |  |  |  |  |
|--|---|--------------|--|--|--|--|--|
| ·  | Application No.   | Applicant(s) |  |  |  |  |  |
| Office Action Commence   | 09/646,224  | GROSE ET AL. |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit     |  |  |  |  |  |
|  | Robert Landsman   | 1647         |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |              |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |  |  |
| Status   |   |              |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 15 Au  | ugust 2005.   |              |  |  |  |  |  |
| <u> </u>   | · · · · · · · · · · · · · · · · · · ·   |              |  |  |  |  |  |
| 3) Since this application is in condition for allowar  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |              |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |              |  |  |  |  |  |
| Disposition of Claims  |   |              |  |  |  |  |  |
| 4)⊠ Claim(s) <u>20 and 22</u> is/are pending in the application.   |   |              |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |              |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |              |  |  |  |  |  |
| 6)⊠ Claim(s) <u>20 and 22</u> is/are rejected.   | ☑ Claim(s) <u>20 and 22</u> is/are rejected.  |              |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  | •   |              |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |   |              |  |  |  |  |  |
| Application Papers   |   |              |  |  |  |  |  |
| 9) In the specification is objected to by the Examiner.  |   |              |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |              |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |              |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |              |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |              |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |              |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> </ul>   |   |              |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |              |  |  |  |  |  |
| Copies of the certified copies of the priority documents have been received in Application No  Copies of the certified copies of the priority documents have been received in this National Stage  |   |              |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |              |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |              |  |  |  |  |  |
|  |   |              |  |  |  |  |  |
|  |   |              |  |  |  |  |  |
| Attachment(s)  |   |              |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date   |   |              |  |  |  |  |  |
| 1) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  5) Notice of Informal Patent Application (PTO-152)   |   |              |  |  |  |  |  |
| Paper No(s)/Mail Date 6) Uther:  |   |              |  |  |  |  |  |

#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/05 has been entered.

#### 1. Formal Matters

- A. The Amendment filed 8/05/05 has been entered into the record.
- B. Claims 20 and 22 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not cited in this Office Action can be found, cited in full, in a previous Office Action.

#### 2. Specification

A. The specification remains objected to since Applicants have not provided an Abstract of the Invention.

## 3. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement

A. The rejection of claims 20 and 22 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove hybridization language and to add the functional limitation that the encoding protein is a sodium channel.

## 4. Claim Rejections - 35 USC § 112, first paragraph - written description

A. The rejection of claims 20 and 22 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove hybridization language and to add the functional limitation that the encoding protein is a sodium channel.

Application/Control Number: 09/646,224 Page 3

Art Unit: 1647

B. Claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation that the encoded protein must encode a human sodium channel. Regardless of this limitation, the claims still read on a polynucleotide encoding a full-length human sodium channel protein. Applicants

have not provided adequate written description of any full-length human protein. Applicants have only

described various isolated fragments of a supposed full-length human sodium channel.

One skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of human sodium channel proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding human sodium channel proteins; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

5. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 20 and 22 under 35 USC 112, second paragraph, has been withdrawn in

view of Applicants' amendments to the claims to remove hybridization language.

6. Claim Rejections - 35 USC § 102

A. The rejection of claim 20 under 35 USC 102, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove hybridization language and to add the functional

limitation that the encoding protein is a sodium channel.

7. Conclusion

A. No claim is allowable.

Art Unit: 1647

## Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on T-F 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman Primary Examiner Art Unit 1647

ROBERT S. LANDSMAN, PH.D PRIMARY EXAMINER